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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,849	06/27/2002	William Hugold Velander	TRANS 1	2472
7590	09/19/2006		EXAMINER	
Peter G. Carroll MEDLEN & CARROLL, LLP 101 Howard street Suite 350 San Francisco, CA 94105			HAMA, JOANNE	
			ART UNIT	PAPER NUMBER
			1632	
			DATE MAILED: 09/19/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,849	VELANDER, WILLIAM HUGOLD	
	Examiner	Art Unit	
	Joanne Hama, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 03 July 2006.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,5-8,11-17,20,22,24,25,27,40,42,44,46,50,53 and 56-59 is/are pending in the application.
 4a) Of the above claim(s) 1,5-8,11-13,16,17,20,22,24,25,27,53 and 59 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 40,42,44,46,50 and 56-58 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Applicant filed a response to the Non-Final Action of December 29, 2006 on July 3, 2006. Claims 2-4, 9, 10, 14, 15, 18, 19, 21, 23, 26, 28-39, 41, 43, 45, 47-49, 51, 52, 54, 55 are cancelled. Claims 1, 5-8, 11-13, 16, 17, 20, 22, 24, 25, 27, 53 are withdrawn. Claims 40, 42, 44, 46, 50, 56-58 are amended. Claim 59 is new.

Newly submitted claim 59 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 59 is a method claim, whereas claims 40, 42, 44, 46, 40, 56-58 are drawn to product claims. While it is not entirely clear what the method claim of 59 is a method for, it has been interpreted as being a method for making the claimed composition. While there is a relationship between the method of making the claimed composition and the composition itself as product and method of making the product, the claim drawn to a method of making the product is separated from the examined claims because in addition to obtaining the composition from a transgenic mammal that secretes the protein in milk, the protein can be made in other ways, such as via expression in bacteria. As such, the product and method of making the product are restricted from each other as distinct inventions.

Accordingly, claim 59 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 40, 42, 44, 46, 50, 56-58 are under consideration.

Withdrawn Rejections

35 U.S.C. § 112, 1st parag.

Applicant's arguments, see pages 7-8 of Applicant's response, filed July 3, 2006, with respect to the rejection of claims 28-31, 33, 35, 36, 40-44, 46, 50, 55-58 have been fully considered and are persuasive. Applicant indicates that the specification contains published references authored by those having ordinary skill in the art describing that a post-translational modification, such as gamma-carboxylation, results in an active prothrombin polypeptide. The rejection of claims 42, 44, 46, 40, 56-58 has been withdrawn. It is noted that the rejections, as they apply to claims 28-31, 33, 35, 36, 41, 43, 55 are withdrawn because these claims have been cancelled.

35 U.S.C. § 102

Applicant's arguments, see page 11, filed July 3, 2006, with respect to the rejection of claims 28, 31, 33, 35, 36, 40, 42, 43, 44, 46, 50, 56, 58 have been fully considered and are persuasive. Applicant indicates that Le Bonniec et al. indicate that, "we cannot conclude that all of the 10 first glutamic residues are modified by the BHK-21 cells (Le Bonniec, et al. page 13799, 1st col., 1st parag.)." The rejection of claims 40, 42, 44, 46, 50, 56, 58 has been withdrawn. It is noted that the rejection of claims 28, 31, 33, 35, 36, 43 are withdrawn as the claims are cancelled.

Applicant's arguments, see page 11, filed July 3, 2006 with respect to the rejection of claims 28-31, 33, 35, 36, 40-44, 46, 50, 56, 58 as being anticipated by Cote et al. in view of Deguchi et al. have been fully considered and are persuasive. Newly

amended claims indicate that the prothrombin be completely gamma-carboxylated. Applicant indicates that Cote et al. teach that the recombinant meizothrombin made in Example 2 was under gamma-carboxylated. The rejection of claims 40, 42, 44, 46, 50, 56, 58 has been withdrawn. It is noted that claims 28-31, 33, 35, 36, 40-43 are withdrawn as the claims are cancelled.

35 U.S.C. 103

Applicant's arguments, see pages 13-15 of Applicant's response, filed July 3, with respect to the rejection of claims 40, 50, and 55 have been fully considered and are persuasive. Applicant has indicated that Morcol and Bell do not disclose that the prothrombin made by Morcol and Bell's transgenic mammalian system, which produces recombinant protein in the milk of transgenic mammals, is completely gamma-carboxylated. The rejection of claims 40, 50, and 55 has been withdrawn.

New/Maintained Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40, 42, 44, 46, 50, 56-58 remain rejected in modified form under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a

way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record, December 29, 2005.

Applicant's arguments filed July 3, 2006 have been fully considered but they are not persuasive.

Applicant indicates that the Examiner summarizes this rejection by stating that, "The primary issue that is being raised in the enablement rejection is similar to that of the written description..." Office Action, page 8. In response, the enablement rejection is maintained as the specification indicates that it is not routine in the art to make completely carboxylated Gla domain prothrombin and nothing in the specification indicates that completely carboxylated Gla domain prothrombin was made.

It is noted that the enablement rejection discussed the fact that the specification does not give guidance for an artisan to arrive at recombinant prothrombin/thrombin that have activity, yet have different structures or characteristics of naturally occurring prothrombin/thrombin encompassed by the claims (i.e. first amino acid sequence, if indeed the protein envisioned is a hybrid or fusion protein, and proteins that are 70% identical to that of human prothrombin/thrombin). This issue was discussed on pages 9-10 of the Office Action. As such, because this issue was not addressed by the Applicant, the rejection remains.

It is also noted that Applicant has indicated that in the rebuttal of the 103 rejection (Applicant's response, July 3, 2006, page 15), that Morcol and Bell, who teach that prothrombin could be one protein that could be expressed in the milk of transgenic mammals, that Morcol and Bell is silent on any post-translational modification (i.e. for

example gamma-carboxylations). Consequently, Morcol and Bell do not teach all the claim limitations. Because Applicant has pointed out this deficiency in Morcol and Bell and has not provided guidance that their system (also a system for expressing prothrombin in milk of transgenic mammals) is distinct from Morcol and Bell and is able to completely gamma-carboxylate prothrombin, Applicant has effectively indicated that the claimed invention is not enabled to completely gamma-carboxylate prothrombin.

It is noted that the rejections, as they apply to claims 28-31, 33, 35, 36, 41, 43, 55 are withdrawn because these claims have been cancelled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40, 42, 44, 46, 50, 56-58 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's arguments, see pages 8-9 of Applicant's response, filed July 3, 2006, with respect to the rejection of claims 28-31, 33, 35, 36, 40-44, 46, 50, 55-58 have been fully considered and are persuasive in part. The rejection of claims 40, 42, 44, 46, 50, 56-58 has been withdrawn in part. It is noted that the rejections, as they apply to claims 28-31, 33, 35, 36, 41, 43, 55 are withdrawn because these claims have been cancelled.

Applicant addresses the issue of using the term "transgenic" to describe polypeptide and indicates that the definition of "transgenic" cited by the Examiner indicates "transgenic" is defined as "of relating to or being an organism..." and that

“relating or related” is defined as “to bring into or link in logical or natural association... or to establish or demonstrate a connection between.” Subsequently because there is an “established connection” that the organism produces the polypeptide, the term “transgenic polypeptide” is properly used. This has been found persuasive and the rejection as it applies to this issue and claim 40 and its dependent claims 42, 44, 46, 40, 56-58 are withdrawn.

Applicant addresses the issue that the term “region” is unclear, as the Examiner had indicated that there are no upper and lower limits as to what comprises a “region.” Applicants amended claims 40 and 44 to recite a first or second “amino acid sequence” instead of a “region.” In response, while Applicant has changed “region” to “first amino acid sequence” and “second amino acid sequence,” the amendment does not address the issue as to what upper limits and lower limits, i.e. lengths or part of amino acids, are encompassed in the claims. As such, the rejection as it applies to this issue remains.

Applicant addresses the issue that the term “identical” is unclear, as the Examiner had indicated that it was unclear if “identical” refers to the amino acid and/or the location of the amino acid in the protein. Applicant indicates that claims 40 and 44 have been amended and that the term “identical” refers to the “amino acid sequence.” In response, the amendment of “amino acid sequence” being added to the claims has not resolved the problem because as indicated above, it is still not clear what metes and bounds are encompassed by the term “amino acid sequence.” The amendments have not addressed the issue raised by using the term “identical” because while the term could mean two protein sequences are “identical” because they have the same domain,

having the same sequence, but the domain occurs in the first half of one protein and in the second half of the second protein. "Identical" is a vague term because it is unclear what criteria is used to identify "identical." As such, the rejection as it applies to this issue remains.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Before responding to Applicant's response to each of the art rejections set forth in the Office Action, December 29, 2006, Applicant generally indicates that *In re Thorpe* provides a holding that is relevant only to the patentability of "product by process claims", not the patentability of "composition claims (Applicant's response, page 10)." In response, the composition claims comprise certain products. In particular for these composition claims, the only requirement of the composition is the prothrombin/thrombin protein. Thus, *In re Thorpe* was cited in the action to indicate that prothrombin/thrombin protein, regardless of how it was made, was taught in the art. While the word, "transgenic" was used in the claims to describe prothrombin/thrombin, "transgenic" does

impart any patentable structural difference to the protein. Unless Applicant shows otherwise, the anticipated art, discussed below, meet the structural limitations of the claims.

Claims 40, 42, 44, 46, 56, 58 remain rejected in modified form under 35 U.S.C. 102(b) as being anticipated by Wu et al., 1997, PNAS, USA, 94: 13654-13660, previously cited.

Applicant's arguments filed July 3, 2006 have been fully considered but they are not persuasive. Applicant disagree that Wu et al. is prior art because the Examiner admits that a transgenic polypeptide is linked in a natural association with a transgenic organism (Applicant's response, page 11, under point B). In response, Wu et al. does anticipate the claimed invention because Wu et al. teach a variety of fusion prothrombin molecules, which structurally fit the limitations of the claims. Regardless of how prothrombin/thrombin was made, Wu et al. teach fusion prothrombin molecules. Also, in light of the amendment of claim 40, wherein the prothrombin is fully gamma-carboxylated, Wu et al. teach that rat and human prothrombin were fully gamma-carboxylated (Wu et al., page 13656, 1st col., 1st parag.). Thus, the rejection is maintained.

It is noted that the rejection of claims 28-31, 33, 35, 36, 41, 43 are withdrawn as the claims are cancelled. It is noted that the rejection of claim 50 is withdrawn because Wu et al. do not teach that the composition further comprises milk.

Claims 40, 42, 44, 46, 56, 58 remain rejected under 35 U.S.C. 102(b) as being anticipated by Wu and Suttie, 1999, Thrombosis Research, 96: 91-98, previously cited, as evidenced by Wu et al., 1997, PNAS, USA, 94: 13654-13660, previously cited.

Applicant's arguments filed July 3, 2006 have been fully considered but they are not persuasive. Applicant disagrees that Wu II as evidenced by Wu I is prior art because the Examiner admits that a transgenic polypeptide is linked in a natural association with a transgenic organism (Applicant's response, page 12, under point D). In response, Wu II, in view of Wu I, does anticipate the claimed invention because Wu II teach various aglyco-rFII (rat prothrombin) fragments that were fully gamma-glutamyl carboxylated; this was shown by BaSO₄ adsorption (Wu et al., page 95, 1st col., 2nd parag.). Wu II teaches that the prothrombin meets the structural limitations of the prothrombin, regardless of how the protein was made. Thus, the rejection is maintained.

It is noted that the rejection of claims 28-31, 33, 35, 36, 41, 43 are withdrawn as the claims are cancelled. It is also noted that the rejection of claim 50 is withdrawn because Wu and Suttie do not teach that the composition further comprises milk.

Claims 40, 42, 44 remain rejected under 35 U.S.C. 102(b) as being anticipated by Wu and Suttie, 1999, Thrombosis Research, 96: 91-98, previously cited.

Applicant's arguments filed July 3, 2006 have been fully considered but they are not persuasive. Applicant disagree that Wu II is prior art because the Examiner admits that a transgenic polypeptide is linked in a natural association with a transgenic

organism. In response, Wu II, does anticipate the claimed invention because Wu II teach various aglyco-rFII (rat prothrombin) fragments that were fully gamma-glutamyl carboxylated; this was shown by BaSO₄ adsorption (Wu et al., page 95, 1st col., 2nd parag.). Wu II teaches the structural limitations of the prothrombin, regardless of how prothrombin/thrombin was made. Because this is a product-by process claim, regardless of how prothrombin/thrombin was made, Wu et al. teach fusion prothrombin molecules. Thus, the rejection is maintained.

It is noted that the rejection of claims 28-30, 33, 35, 36, 41 are withdrawn because the claims are cancelled. It is also noted that the rejection of claim 50 is withdrawn because Wu and Suttie do not teach that the composition further comprises milk.

Claims 40, 44, 57 remain rejected under 35 U.S.C. 102(b) as being anticipated by Seegers et al., 1950, Blood, 5: 421-433, previously cited.

Applicant's arguments filed July 3, 2006 have been fully considered but they are not persuasive. Applicant indicates that Seegers et al. is not prior art because Seegers et al. does not teach any recombinant prothrombin (Applicant's response, page 13). In response, regardless of how prothrombin/thrombin was made, Seegers et al. teach that prothrombin was isolated from bovine plasma and that it was treated with sodium citrate. It is noted that while Seegers et al. are silent as to whether the prothrombin is completely gamma-carboxylated. As far as the Examiner can tell, the prothrombin taught by Seegers et al. is completely gamma-carboxylated and cannot determine

otherwise. It is noted that the PTO lacks the ability to manufacture products or to obtain and compare prior art products. As such, the rejection is maintained.

It is noted that the rejection of claims 28, 33, 36 are withdrawn because the claims are cancelled. It is also noted that the rejection of claim 50 is withdrawn because Wu and Suttie do not teach that the composition further comprises milk.

Claims 40, 42, 44, 57 remain rejected under 35 U.S.C. 102(b) as being anticipated by Vogel et al., 1976, Biochemistry, 15: 3265-3269, previously cited.

Applicant indicates that Seegers et al. is not prior art because Seegers et al. does not teach any recombinant prothrombin (Applicant's response, page 13). In response, regardless of how prothrombin/thrombin was made, Vogel et al. teach that bovine prothrombin was treated with factor Xa and polylysine. As far as the Examiner can tell, the prothrombin taught by Vogel et al. is completely gamma-carboxylated and cannot determine otherwise. It is noted that the PTO lacks the ability to manufacture products or to obtain and compare prior art products. As such, the rejection is maintained.

It is noted that the rejection of claims 28, 33, 36 are withdrawn because the claims are cancelled. It is also noted that the rejection of claim 50 is withdrawn because Wu and Suttie do not teach that the composition further comprises milk.

Claims 40, 42, 44, 57 remain rejected under 35 U.S.C. 102(b) as being anticipated by Landaburu and Seegers, 1958, Am. J. Physiol. 193: 169-180.

Applicant indicates that Landaburu and Seegers is not prior art because Landaburu and Seegers do not teach any recombinant prothrombin (Applicant's response, page 13). In response, regardless of how prothrombin/thrombin was made, Landaburu and Seegers teach that purified bovine prothrombin in the presence of sodium citrate or protamine sulfate or purified platelet factor 3. As far as the Examiner can tell, the prothrombin taught by Landaburu and Seegers is completely gamma-carboxylated and cannot determine otherwise. It is noted that the PTO lacks the ability to manufacture products or to obtain and compare prior art products. As such, the rejection is maintained.

It is noted that the rejection of claims 28, 33, 36 are withdrawn because the claims are cancelled. It is also noted that the rejection of claim 50 is withdrawn because Wu and Suttie do not teach that the composition further comprises milk.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 40, 42, 44, 46, 56-58 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Wu and Suttie, 1999, Thrombosis Research, 96: 91-98, in view of Seegers et al., 1950, Blood, 5: 421-433, previously cited.

Wu et al. teach that rat and human prothrombin were completely gamma-carboxylated (Wu. et al., page 95, 1st col., 2nd parag.) and that prothrombin was N-glycosylated (Wu et al., abstract). Wu et al. also teach that the prothrombin underwent proteolytic processing (Wu et al., page 93-94 under 2.2. Specific Proteolytic Processing of Aglyco-rFII in HEK293 Cells). While Wu et al. teach these characteristics of rat and human prothrombin, they do not teach that proteolytic processing is carried out in the presence of sodium citrate.

Seegers et al., teach the activation of prothrombin when treated with sodium citrate. Seegers et al. teach that purified prothrombin in a 25 per cent solution of sodium citrate yield measurable amounts of thrombin after 5 hours of treatment and that soon thereafter, activation of prothrombin is rapid (Seegers, et al., page 421, 3rd parag.).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to add sodium citrate to a composition comprising prothrombin.

One having ordinary skill in the art would have been motivated to add sodium citrate to prothrombin, in order to arrive at activated thrombin.

There would have been a reasonable expectation of success given the Wu et al. for teaching rat and human prothrombins that are completely gamma-carboxylated and is N-glycosylated and Seegers et al. for teaching that prothrombin is activated in the presence of sodium citrate.

Conclusion

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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JH

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

